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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/637,149	08/08/2003	**Gerald E. McDonnell**	MEDZ 2 01304	3426

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EXAMINER	
HORNING, MICHELLE S	
ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/637,149	MCDONNELL ET AL.	
	Examiner	Art Unit	
	MICHELLE HORNING	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,15-18,22,23 and 25-30* is/are pending in the application.

4a) Of the above claim(s) *2-4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5-13, 15-18, 22, 23 and 25-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is responsive to communication filed 6/25/2009. The status of the claims is as follows: claims 1-13, 15-18, 22, 23 and 25-30 are pending, claims 2-4 are withdrawn and claims 1, 5-13, 15-18, 22, 23 and 25-30 are under current examination.

Claim Rejections - 35 USC § 103-MAINTAINED

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1, 5-13, 15-18, 22, 23 and 25-30 under 35 U.S.C. 103(a) as being unpatentable over Foster (US Patent No. 7252720), Ernst and Race (J Virological Methods, 1993) and Kritzler (US Patent Application 10/467591) is maintained as set forth by the previous action mailed out 3/30/2006.

Response to Arguments

Applicant's arguments filed 6/25/2009 have been fully considered but they are not persuasive. Applicant contends that the Office has failed to establish a *prima facie* case of obviousness and that the references alone or in combination do not suggest the claimed method (Remarks, p. 8-9). The arguments are addressed below.

Applicant states that the Foster reference discloses a method for removing contamination from ion-exchange chromatography columns by using sodium chloride to elute and remove the prions from the column. Applicant further notes that Foster demonstrates little or no conformational change of prions following a 2M sodium chloride wash. Applicant notes that Foster fails to teach use of a phenol; see throughout Remarks, p. 6-12.

In addition to removing prions from chromatography columns as noted by Applicant, Foster describes a method of cleaning a reusable substrate, including medical and surgical instruments, via washing the substrate with a salt solution thereby removing the prions from the substrate (abstract, col. 3, lines 1-5). With respect to Applicant's argument that the teachings by Foster demonstrate little or no conformational change of prions, Foster provides that no prion infectivity was detected in a sample following a second NaCl wash (col. 6, lines 55+); accordingly, a longer exposure of NaCl leads to no detectable prion infectivity. Note that a change in a protein's function (e.g. lack of infectivity or ability to be retained by a column) is correlated to a change in its structure (e.g. prion conformation). Thus, this reference provides at least two rationales for one of ordinary skill in the art to use salt in a

composition for treating a body contaminating with infectious prions, including removing or displacing prions from the substrate or body and elimination of prion infectivity. While this reference does not describe the use of phenols, Ernst and Race was cited for teaching this specific limitation.

With respect to the teachings of Ernst and Race, Applicant states that authors provide no teaching of using an inorganic salt. Applicant also notes that the authors use LpH a solution which comprises a halogenated phenol as well as non-halogenated phenols for the treatment of infectious prions (or scrapie). Applicant submits that the authors provide no suggestion that the composition would be effective against prions without the halogenated phenol. Lastly, Applicant points out that later work by Race and Gregory advise against using compositions which lack o-benzyl-p-chlorophenol; see Remarks, p. 7-12.

With respect to later work by Race and Gregory in which Applicant submits the authors advise against not using compositions which lack o-benzyl-p-chlorophenol, a halogenated phenol, Applicant is reminded that a known composition does not become patentable because the composition has been described as inferior. See MPEP 2123. Also, Ernst and Race specifically teach that it is only the phenols in the LpH compositions that provide the prion decontamination results and given there are only two phenols present, one of ordinary skill in the art would have clearly thought that one or both was capable of performing the deactivation of the prions. Ernst and Race also teach that phenols are somewhat toxic, thus one of ordinary skill in the art would have looked to see which phenol of the two in this reference is active in order to limit the

potential toxic affect. Also, the art taken as a whole teaches the use of various phenols for deactivating prions, note that Kritzler teaches the use of cresol for deactivating prions, and cresol is a non-halogenated phenol, cresol is methylphenol.

Kritzler teaches a method and a composition for treating a surface contaminated with a scrapie prion protein. Applicant submits that Kritzler discloses that certain surfactants tend to bind to proteins and initiate their unfolding and inorganic salts can induce conformational transitions in proteins. Applicant submits that these teachings however detail the understanding about proteins in general or "conventional proteins" and not about prion proteins. Applicant further notes that such general assumptions do not apply to prions as represented by models of proteins including bovine albumin of Table 1; see Remarks, p. 7-12.

In response, the use of surfactants and inorganic salts as agents in protein unfolding are conceived inventions of the prior art as shown by Kritzler. The evidence in supporting Applicant's contention that use of these agents does not apply to prions is unclear. Given Applicant suggests that such general assumptions regarding protein unfolding does not apply to prion but does apply to other proteins, including bovine albumin (BSA), Applicant is invited to read p. 12, lines 27+ of the instant specification which provides the following recitation: "The effectiveness of various formulations of the composition may be investigated using human or other animal prion. Alternatively, a prion model, e.g., a protein such as bovine serum albumin (BSA) may be used to evaluate formulations." Thus, according to the instant specification, BSA may be used as a prion model in evaluating formulations.

Applicant argues that Kritzler discusses cresol (a non-halogentated phenol) to proteins in general and thus would not expect that it could cause conformational changes in prions.

This is not found persuasive. Of note, the title of the Kritzler patent is "Prion Disinfection" and the use of the cresol in this patent is directed to the disinfection of prions. While the Kritzler patent also teaches the use of an enzyme, it is noted that the instant claims include the term "comprising" and are not limited to the inclusion of additional steps. While the use of halogenated phenol is excluded, Kritzler specifically teaches the use of a non-halogenated phenol in methods of prion disinfection.

Applicant asserts that for claim 11, Foster does not teach the salt treatment destroys proteins.

This is not found persuasive because Foster teaches a method of removing prion activity using salt solutions. Clearly, the addition of salt is an important step in the disinfection of proteins, such as, prions, as shown by the cited art.

Applicant also asserts as to claim 11, that Ernst and Race fail to disclose that the salt would improve the activity of the phenol.

This is not found persuasive. Combining two agents for the same purpose is prima facie obvious and the use of salts and phenol compositions for prion disinfection is well known as shown by the cited references. The argument that the salt must *improve* the phenol activity appears to suggest that synergism must be present. But a synergistic effect is not required for a combining two agents taught in the art for the

same purpose. Note, applicant has not provided any showing that the salt *improves* the effects of the phenol composition.

Applicant separately argues claims 13, 23, 29 and 30 but provides the same arguments as addressed above. Thus these arguments are addressed hereinabove.

Note that it is obvious to combine equivalents for the same purpose. In the instant invention, inorganic salts, phenols and surfactants are conceived as agents that alter protein conformation in the prior art. See MPEP 2144.06.

I. < COMBINING EQUIVALENTS KNOWN FOR THE SAME PURPOSE

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Further noted is that the recitation "to effect a change in the three dimensional structure of the prion protein and to inactivate prions on the body" in the claims (see instant claim 1) is not an active step of the claimed methods, but only the mechanisms of action which occur by the active step of contacting a body with a composition comprising a phenol and an inorganic salt. The prior art discloses the same active steps of the instant claims, thus, the same mechanisms of action must occur because the composition/method use and its properties are inseparable.

Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view

of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. H./
Examiner, Art Unit 1648

/Zachariah Lucas/
Primary Examiner, Art Unit 1648